

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/398,522	ISSA, JEAN-PIERRE	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jeanine A Goldberg	1634	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 7/16/03.
2. ☒ The allowed claim(s) is/are 10,19,21-23,33 and 37-42.
3. ☒ The drawings filed on 15 September 1999 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.**

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)  | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 4 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____    |
| 5 <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. <u>403</u> . | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment         |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material     | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|  | 9 <input type="checkbox"/> Other _____                                     |

### **REASONS FOR ALLOWANCE**

1. This action is in response to the papers filed July 16, 2003. Currently, claims 10, 19, 21-23, 33 and 37-42 are pending.

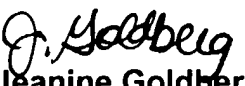
#### ***Maintained Rejections***


2. The following is an examiner's statement of reasons for allowance.

Claim 10 has been amended to recite colorectal adenoma or cancer other than glioma. On page 25 and 28 of the instant specification, the specification teaches that regions 1 and 2 were frequently methylated and these 2 regions were methylated in most cancer cell types except gliomas (page 25, lines 16-18). The specification teaches sampling a large number of primary cancers including colorectal, colorectal adenomas, primary gastric cancers and AML samples. Moreover 35 cell lines from colon, lung, prostate, breast and hematopoietic tumors were analyzed. The evidence provided in the specification enables the skilled artisan to amplify either the first or second region of the CACNA1G CpG island with SEQ ID NO: 33-36 and compare and determine methylation as indicative of cancer or colorectal adenoma.

Similarly, as explained in the response, the 5<sup>th</sup>, 6<sup>th</sup>, and 7<sup>th</sup> regions of the CpG island of CACNA1G showed aberrant methylation in colorectal cancers, colorectal adenomas, gastric cancers and AML (page 27, lines 17-20). The evidence provided in the specification enables the skilled artisan to amplify either the 5<sup>th</sup>, 6<sup>th</sup> or 7<sup>th</sup> region of the CACNA1G CpG island with SEQ ID NO: 41-45 and compare and determine methylation as indicative of colorectal cancers, colorectal adenomas, gastric cancers and AML.

3. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."
4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 6:00 a.m. to 3:30 p.m.
- If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.
- Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
**Jeanine Goldberg**  
**Patent Examiner**  
October 7, 2003

  
**GARY BENZION, PH.D.**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**